UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENUS LIFESCIENCES INC., Plaintiff, v. LANNETT COMPANY, INC., Defendant.	C.A. No. 20-770-LPS JURY TRIAL DEMANDED [redacted]

LANNETT COMPANY, INC.'S MEMORANDUM OF LAW IN OPPOSITION TO GENUS LIFESCIENCES INC.'S MOTION TO DISMISS COUNTERCLAIMS

Dated: August 14, 2020

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INTRODUCTION

As Lannett alleges in its counterclaims, Genus repeatedly demanded that Lannett pay substantial royalties for a license to its patents covering cocaine hydrochloride products, implicitly threatening suit to enforce them if Lannett refused to accede to its demands. When Lannett refused, and advised Genus it would instead challenge the validity of Genus's patents, Genus made good on its threat and commenced this action. But Genus wants to hold some of its patents in reserve—all related to the same technology—hoping to insulate them from Lannett's invalidity challenges so it can deploy them in the future against Lannett and potential generic competitors. For that reason, Genus sued on only three of the six patents it listed in the FDA's Orange Book with respect to GOPRELTO, its branded cocaine hydrochloride product.

In response, Lannett filed counterclaims seeking declarations of invalidity and/or non-infringement as to all of Genus's Orange Book-listed patents, so as to obtain clarity regarding its freedom to continue to make and sell cocaine hydrochloride products free and clear of Genus's patent threats. Genus responded by granting Lannett a covenant not to sue (the "Partial Covenant") that is carefully circumscribed so as to leave Genus free to sue Lannett based on claims in four of Genus's Orange Book-listed patents at a later time and place of its choosing. Indeed, it is so full of caveats and exclusions that it does not prevent Genus from asserting ***any*** of its patent claims against the product Lannett is currently selling – even those ostensibly subject to the covenant. Genus also moved to dismiss Lannett's counterclaims insofar as they relate to any patents or patent claims not affirmatively asserted by Genus in its Complaint. In other words, Genus wants to be able to dictate exactly when, where and how it will deploy its patent assets against Lannett so as to best suit its strategic purposes.

Fortunately for Lannett, the law does not grant that power to Genus, and Genus's machinations do not forestall this Court's jurisdiction over Lannett's well-founded

counterclaims. If anything, Genus' tactics heighten the case and controversy between the parties. By only putting some of its patent claims into play, while providing a "covenant not to sue" that is carefully constructed so as to preserve its ability to enforce its additional as yet unasserted patents and patent claims in the future, Genus has demonstrated its intent to hold those patents over Lannett's head like the Sword of Damocles, until such time and place as it is in Genus's unilateral strategic interest to deploy them.

The facts Lannett has alleged are more than sufficient to sustain this Court's exercise of subject matter jurisdiction over all of its counterclaims. Genus is attempting to create a cloud of on-going uncertainty regarding Lannett's freedom to continue selling its cocaine hydrochloride products, but Lannett is entitled to have that cloud removed.

NATURE AND STATE OF THE PROCEEDINGS

Genus sued Lannett for infringement of three of its Orange Book-listed patents, based on Lannett's sales of its NUMBRINO product. In response, Lannett filed counterclaims seeking declarations of non-infringement and invalidity with respect to those three patents, as well as Genus's three additional, as yet unasserted Orange Book-listed patents, and including a declaration of non-infringement with respect to Lannett's prior C-TOPICAL product, which is identical to and administered in the same way as its current NUMBRINO product.

Genus moves to dismiss Lannett's counterclaims to the extent they relate to any patent or claim of infringement not yet actually asserted by Genus. In particular, Genus posits three grounds for dismissing some, but not all, of Lannett's counterclaims: (1) that the Partial Covenant moots any controversy as to the as yet unasserted patent claims of the '815 and '407 patents it is asserting in this case; (2) that there is no justiciable controversy regarding Genus's as yet unasserted Orange Book-listed patents (*i.e.*, the '843, '961 and '505 patents); and (3) that there is no justiciable controversy regarding Lannett's C-TOPICAL product.

SUMMARY OF ARGUMENT

1. Lannett has pled facts sufficient to demonstrate the existence of an actual, substantial controversy regarding the invalidity and alleged infringement of all six of Genus's Orange Book-listed patents, which is of sufficient immediacy and reality to sustain this Court's jurisdiction over all of Lannett's counterclaims. The Court can and should exercise that jurisdiction, and deny Genus's motion.

2. None of the three grounds for Genus's motion has merit: (1) Genus's Partial Covenant does not even cover the cocaine hydrochloride product that Lannett is currently selling, and is thus completely ineffectual and effectively meaningless; (2) all six of Genus's Orange Book-listed patents relate to the same technology, such that there is a definite and concrete dispute between the parties as to all of those patents, not just those that Genus has chosen—for now—to assert; and (3) Lannett's prior C-TOPICAL product is identical to, and used in the same way as, its current NUMBRINO product, such that the same actual and substantial controversy that exists as to NUMBRINO also exists as to C-TOPICAL.

3. The fact that Genus has not yet overtly threatened to sue Lannett with respect to its as yet unasserted patents and patent claims does not forestall this Court's jurisdiction over Lannett's counterclaims.

STATEMENT OF FACTS

A. Cocaine Hydrochloride Products

Cocaine hydrochloride, the active ingredient in all of the products at issue, is a local anesthetic and vasoconstrictor commonly used in connection with many different types of diagnostic and surgical procedures. D.I. 6 (Lannett Counterclaims), ¶ 9. This has been so for well over a century—as the FDA observed, "[s]ince the 1880s, cocaine has been used clinically

in nasal and sinus surgery as a topical anesthetic and vasoconstrictive agent." Ex. 1[1] (FDA Response to Genus Citizen Petition (Jan. 10, 2020)) at 3. Indeed, a 1977 review article noted that "[c]ocaine…produces excellent anesthesia and vasoconstriction of mucous membrane surfaces. Every nasal surgeon is well aware of this, most relying on it exclusively as their anesthetic of choice for nasal surgery." Ex. 2 at 1. Over the years, a variety of manufacturers have sold cocaine hydrochloride formulations in the United States. D.I. 6 (Lannett Counterclaims), ¶ 9.

Lannett's C-TOPICAL Product: In 2008—years before Genus applied for its patents, Lannett began selling a cocaine hydrochloride product under the tradename "C-TOPICAL®." *Id.*, ¶ 10. As per its label, C-TOPICAL was used for "the introduction of local (topical) anesthesia of accessible mucous membranes of the oral, laryngeal, and nasal cavities." *Id.*, Ex. 1. C-TOPICAL was used by physicians for various types of nasal and other procedures. *Id.*, ¶ 10.

Lannett's NUMBRINO Product: C-TOPICAL was not approved by the FDA, but was marketed subject to the FDA's enforcement discretion for over a decade.[2] *Id.*, ¶ 11. Consistent with the FDA's encouragement to manufacturers of unapproved drugs to seek FDA approval for them, in September 2017, Lannett submitted NDA No. 209575, under §505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking FDA approval for its cocaine hydrochloride product, under the tradename "NUMBRINO®." *Id.* NUMBRINO is the same product as

[1] "Ex. __" refer to the Declaration of Robert Rhoad filed contemporaneously herewith.

[2] Genus tries to smear Lannett by characterizing C-TOPICAL as an "illegal" product that Lannett was "forced" to withdraw, as if Lannett were an illicit drug dealer selling cocaine on a street corner. In reality, upon a request in 2019 by the FDA (which had been aware of Lannett's unapproved C-TOPICAL product for years, but had taken no action to remove it from the market), Lannett voluntarily agreed to cease manufacturing and distributing C-TOPICAL. As the court recognized in Genus's Lanham Act litigation against Lannett, "Genus's apparent attempt to add a sheen of criminality" to Lannett's sales of C-TOPICAL "is not well taken." *Genus Lifesciences Inc. v. Lannett Co., Inc.*, 378 F. Supp. 3d 823, 827 n.1 (N.D. Cal. 2019).

Lannett's prior C-TOPICAL product—it is made with the same components, using the same manufacturing process, and is packaged in the same containers as C-TOPICAL was. *Id.* Lannett ceased selling C-TOPICAL in August 2019, and currently only sells NUMBRINO. *Id.*, ¶ 21.[3]

Genus's GOPRELTO Product: Genus wanted to enter the cocaine hydrochloride market, but had no product of its own. *Id.*, ¶ 17. In September 2016, Genus acquired a previously-filed Investigational New Drug Application for a cocaine hydrochloride product named GOPRELTO from a third party. *Id.* Two months later, Genus filed a §505(b)(2) NDA, seeking approval to sell GOPRELTO based on, among other things, the extensive history of the safe and effective use of various cocaine hydrochloride products, including Lannett's C-TOPICAL product, in nasal and other surgeries and diagnostic procedures. *Id.*, ¶¶ 18-19.

GOPRELTO is comprised of the exact some components, [redacted] in the same dosage form (aqueous solution) and strength (4%), as both Lannett's pre-existing C-TOPICAL product and its current NUMBRINO product:

Component	C-TOPICAL	NUMBRINO	GOPRELTO
Cocaine HCl	40 mg/ml (4%)	40 mg/ml (4%)	40 mg/ml (4%)
Sodium benzoate	[redacted]	[redacted]	[redacted]
Citric acid	[redacted]	[redacted]	[redacted]
D&C Yellow No. 10	[redacted]	[redacted]	[redacted]
FD&C Green No. 3	[redacted]	[redacted]	[redacted]
Water	[redacted]	[redacted]	[redacted]

[redacted]

[3] As described below, Genus obtained approval for its cocaine hydrochloride product in December 2017, before Lannett's NDA was approved. The FDA's request that Lannett cease selling C-TOPICAL was consistent with the agency's practice of asking manufacturers of unapproved products to withdraw their products from the market at some point after an approved form of the product is available. *Id.* n.1.

[redacted] Moreover, all three products are administered in exactly the same way (soaking four pledgets with the cocaine hydrochloride solution and placing them in the patient's nasal cavity), for the same purpose (local anesthesia), in connection with nasal diagnostic and surgical procedures.[5]

B. Genus's Patents

Genus obtained six patents related to GOPRELTO: U.S. Patent Nos. 9,867,815 ("the '815 Patent"), 10,016,407 ("the '407 Patent"), 10,149,843 ("the '843 Patent"), 10,231,961 ("the '961 Patent"), 10,413,505 ("the '505 Patent"), and 10,420,760 ("the '760 Patent") (collectively the "Patents in Suit"). *See* D.I. 6, Exs. 3-8. All six patents claim priority back to the same parent application, and are continuations or continuations-in-part from that application. *See id.* They all have the same Title, the same Abstract, and substantially overlapping specifications and claim limitations. *See id.* Genus has listed all six of the Patents in Suit in the FDA's Orange Book with respect to GOPRELTO. D.I. 6 (Lannett Counterclaims), ¶ 23.

C. Genus's Litigations and Demands that Lannett License Its Patents

This case is merely the latest gambit in Genus's broader strategy to insulate its GOPRELTO product from competition, which has included, among other things, the following:

- In February 2019, Genus filed a Citizen's Petition with the FDA seeking to

[4] [redacted]

[5] *See* Ex. 5 (GOPRELTO Label) at 1 ("Indications and Usage," "Dosage and Administration"); Ex. 6 (NUMBRINO Label) at 1 ("Indications and Usage" and "Dosage and Administration"); D.I. 6, Ex. 1 (C-TOPICAL Label) at 1 (used for "the introduction of local (topical) anesthesia of accessible mucous membranes of the oral, laryngeal, and nasal cavities"); Ex. 7 (compilation of case studies describing the use and administration of C-TOPICAL).

preclude the FDA from further considering or approving Lannett's 505(b)(2) NDA for NUMBRINO product; the FDA denied that petition (*see* D.I. 6 (Lannett Counterclaims), ¶ 32; Ex. 8 (FDA denial of February 2019 petition));

- In August 2019, Genus filed a second Citizen Petition requesting (in part) that the FDA rescind its acceptance of Lannett's NUMBRINO NDA; the FDA denied that petition as well (*see* D.I. 6 (Lannett Counterclaims), ¶ 32; Ex. 1 (FDA denial of August 2019 petition));

- In November 2019, Genus sued Mallinckrodt, its active ingredient supplier, seeking to preclude Mallinckrodt from supplying cocaine hydrochloride to other companies who may wish to make and sell cocaine hydrochloride products in competition with Genus (*see* D.I. 6 (Lannett Counterclaims), ¶ 33);

- In January 2020, Genus sued the FDA and others seeking an order requiring the FDA to rescind its approval of NUMBRINO (*see id*, ¶ 32);

- Genus has also sued Lannett directly, alleging violations of federal and state antitrust, false advertising, and unfair competition laws (*see id*, ¶ 34).

During the course of discussions regarding possible resolution of Genus's multi-front litigation campaign to insulate GOPRELTO from competition, Genus has repeatedly demanded that Lannett pay substantial royalties for a license to its "current and future patents covering cocaine hydrochloride." *See* Genus Ex. B at 2; D.I. 6 (Lannett Counterclaims), ¶¶ 29-31, 35. Those patents include all six of the patents that Genus listed in the Orange Book for GOPRELTO. Indeed, by listing them in the Orange Book, Genus has represented to the FDA both (a) that all six patents cover cocaine hydrochloride products and/or methods of using them, and (b) that a claim of patent infringement could reasonably be asserted against any entity—such as Lannett—that engages in the manufacture, use, or sale of a cocaine hydrochloride solution product without a license.[6] Genus's demands were intended to and did carry an implicit threat

[6] *See* 21 U.S.C. § 355(b)(1) (requiring that a new drug applicant identify "the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug").

that if Lannett failed to accede to Genus's demands, Genus would seek to enforce its Orange Book-listed patents and recover those royalties from Lannett via litigation. *Id.*, ¶ 30.

When Lannett refused to accede to Genus's demands, and instead asserted that Genus' patents were not enforceable, Genus acted on its implied threat, and commenced this patent infringement suit. But, Genus held back some of its Orange Book-listed patents, so as to insulate them from Lannett's invalidity challenges and keep them in its back pocket for use in future litigation, against Lannett or possible future generic competitors.

D. Genus's Partial Covenant

In connection with its motion, Genus granted Lannett a carefully-crafted, partial covenant not to sue designed to further its plans to protect some of its Orange Book-listed patents from this Court's scrutiny and thereby preserve them for use in the future. D.I. 14, Ex. A. That covenant is expressly limited, for example, to a handful of claims in two of Genus's patents (the "Covenanted Claims"), and to the NUMBRINO product sold before July 24, 2020 if sold with product label attached as Ex. D to the Complaint (definition of "Lannett Product"). *Id.* Thus, it does not cover, for example, any NUMBRINO product sold with a label that has been "changed, amended, or modified in any way." *Id.* It also is limited to Lannett and its "affiliates," such that it does not protect Lannett's wholesalers, customers, or end-users.

ARGUMENT

I. GOVERNING LEGAL STANDARDS

Genus has filed a Rule 12(b)(1) motion challenging this Court's jurisdiction over Lannett's counterclaims under the Declaratory Judgment Act. Pursuant to that Act,[7] federal

[7] The Act provides that: "In a case of actual controversy within its jurisdiction ... any court in the United States ... may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

courts have jurisdiction over declaratory judgment counterclaims, like those Lannett alleges here, if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)). In *MedImmune*, the Supreme Court rejected the more stringent "reasonable apprehension of suit" test that the Federal Circuit had applied, such that "a specific threat of infringement litigation by the patentee is not required to establish jurisdiction, and a declaratory judgment action cannot be defeated simply by the stratagem of a correspondence that avoids magic words such as 'litigation' or 'infringement.'" *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (internal quotations omitted). "'[A]n examination of the totality of the circumstances must be made to determine whether there is a controversy' in a patent declaratory judgment action." *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330-31 (Fed. Cir. 2014) (citation omitted).

A Rule 12(b)(1) motion challenging subject matter jurisdiction may present either a facial challenge or a factual challenge to the Court's jurisdiction. *See Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014). A facial attack "considers a claim on its face and asserts that it is insufficient to invoke the subject matter jurisdiction of the court…" *Id.* at 358. "In reviewing a facial attack, the court must only consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the [claimant]." *Gould Elecs. Inc. v. U.S.*, 220 F.3d 169, 176-77 (3d Cir. 2000). On the other hand, a factual attack argues "there is no subject matter jurisdiction because the facts of the case—and here the District Court may look beyond the pleadings to ascertain the facts—do not support the asserted jurisdiction." *Constitution Party of Pa.*, 757 F.3d at 358.

Genus primarily presents a facial attack on Lannett's counterclaims because its motion "focus[es] on the allegations in [Lannett's Counterclaims] and why those allegations assertedly do not give rise to subject matter jurisdiction." *In re Mobile Telecomms. Techs., LLC*, 247 F. Supp. 3d 456, 459 (D. Del. 2017). Genus argues, for instance, that "Lannett's Counterclaims omit any factual allegations showing an 'actual controversy' as to" the '843, '961, and '505 Patents. D.I. 13 at 10; *see also id.* at 12 (arguing that "Lannett has failed to plead any facts showing 'affirmative acts' by Genus as to C-Topical that create an actual, substantial controversy"). Accordingly, in assessing those arguments, the Court "must accept as true all material allegations set forth in the [counterclaims], and must construe those facts in favor of the [counterclaiming] party." *Constitution Party of Pa.*, 757 F.3d at 357 n.12 (quoting *Storino v. Borough of Point Pleasant Beach*, 322 F.3d 293, 296 (3d Cir. 2003)).

II. THIS COURT HAS SUBJECT MATTER JURISDICTION OVER ALL OF LANNETT'S COUNTERCLAIMS

Genus seeks to dismiss Lannett's Counterclaims to the extent they relate to any patents or infringement claims not actually asserted in Genus's Complaint, and posits three grounds for doing so (*see* description above). None has merit.

A. Genus's Partial Covenant Is Completely Ineffectual

"Whether a covenant not to sue will divest the trial court of jurisdiction depends on what is covered by the covenant." *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 556 F.3d 1294, 1297 (Fed. Cir. 2009). The Supreme Court's seminal opinion in *Already, LLC v. Nike, Inc.*, 568 U.S. 85 (2013), is illustrative.[8] In that case, Nike sued Already alleging that certain shoe lines

[8] Although *Already* concerns a claim of trademark infringement, its principles apply with equal force to covenants not to sue for patent infringement. *See Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1358 (Fed. Cir. 2013).

designed and marketed by Already infringed and diluted Nike's trademark, and Already filed a counterclaim asserting that the trademark was invalid. *Id*. at 88. In response, Nike issued a covenant not to sue and moved to dismiss its own claims, as well as Already's counterclaim. The covenant covered not only Already's existing footwear designs, but also "any future Already designs that constituted a 'colorable imitation' of Already's current products." *Id*. at 89. Noting that "it was Nike's burden to show that it 'could not reasonably be expected' to resume its enforcement efforts against Already" (*id*. at 92 (citation omitted)), the Court examined the language of the proposed covenant and found that Nike met that burden because its covenant was "unconditional and irrevocable. Beyond simply prohibiting Nike from filing suit, it prohibits Nike from making any claim *or* any demand. It reaches beyond Already to protect Already's distributors and customers. And it covers not just current or previous designs, but any colorable imitations." *Id*. at 93 (emphasis original).

As explained in *AstraZeneca LP v. Breath Ltd.*, the key factors leading to the Supreme Court's finding that the covenant in *Nike* mooted the parties' controversy "included: (1) the covenant's unconditional and irrevocable nature, (2) its prohibition on any claim or demand, (3) the inclusion of the covenant recipient's distributors and customers, and (4) the breadth of the prohibition covering present and future designs." C.A. No. 08-1512 (RMB/AMD), 2013 WL 2404167, at *3 (D.N.J. May 31, 2013). Accordingly, where parties have tried to forestall a court's jurisdiction by granting more limited covenants, courts have found them insufficient.[9]

[9] *See, e.g., id.*; *ActiveVideo Networks, Inc. v. Trans Video Elecs., Ltd.*, 975 F. Supp. 2d 1083, 1095-96 (N.D. Cal. 2013) (denying motion to dismiss where patentee "steadfastly refuse[d] to include AV's customers in its covenant not to sue, yet has failed to explain why it has chosen to do so if it has no plans to sue"); *SanDisk Corp. v. Mobile Media Ideas LLC*, No. C 11-00597 CW, 2011 WL 1990662, at *2 (N.D. Cal. May 23, 2011) (finding proposed covenant not to sue insufficient, as it "does not eliminate the possibility that SanDisk's customers may face a patent infringement lawsuit by [patentee]").

AstraZeneca is directly on point. The covenant at issue only applied to Apotex's ANDA product as it existed on a particular date, expressly did not apply to other products or if any changes were made to Apotex's product, and it was deficient in other respects:

> Unlike in *Nike*, AstraZeneca's covenant does not state that it is unconditional and irrevocable and does not cover its suppliers, distributors, and customers. Further, and most importantly, it only covers Apotex's [ANDA] *as originally filed* with the FDA *as of a particular date*. Apotex represents that it has already amended or supplemented its ANDA and that the relevant filing date has changed, so the covenant does not even cover its current ANDA.

Id. As the court recognized, the problem Apotex faced in view of the limited covenant proffered by AstraZeneca was that absent the ability to have the court adjudicate its claim that AstraZeneca's patents were invalid, it would be forced to choose between engaging in allegedly illegal behavior by selling an allegedly infringing product, or abandoning the sale of its product even though it believed it had a right to do so. *Id.* at *4. Accordingly, the court held that AstraZeneca had failed to show that it could not reasonably be expected to resume its enforcement efforts against Apotex, and therefore denied AstraZeneca's motion to dismiss Apotex's invalidity counterclaims.

Here, Genus's Partial Covenant is similarly deficient, as it too does not even cover the accused product at issue in the case. Genus narrowly defined the "Lannett product" covered by its Partial Covenant such that it "does not include any product wherein the Prescribing Information attached as Exhibit D to the Complaint … is changed, amended, or modified ***in any way***." D.I. 14, Ex. A, at 1 (emphasis added). In other words, Genus wanted to remain free to sue Lannett if Lannett ever made ***any*** change to the original NUMBRINO label, no matter how insignificant or irrelevant the change may be to any issues relating to Genus's patents, knowing that the labels for pharmaceutical products are routinely amended for any number of reasons.[10]

[10] *See, e.g.*, by way of example only: 21 U.S.C. § 355(o)(4) (regarding safety-related labeling

In fact, Lannett has already amended the version of the NUMBRINO label cited in the Partial Covenant so as to remove certain "Contraindications" from the "Highlights of Prescribing Information" page of the label. *Compare* Ex. 6 (current NUMBRINO Label) at 1, *with* Ex. D to Complaint, at 1 (D.I. 1-1 at Page ID #: 191). Thus, like the covenant in *AstraZeneca*, Genus's Partial Covenant is, for all practical purposes, completely ineffectual and meaningless.

Genus's Partial Covenant is also chock full of other holes. It does not apply, for instance, to any claims of the three as yet unasserted Orange Book-listed patents, or even to all of the unasserted claims of the three patents on which Genus has sued Lannett (it covers the unasserted claims of the '815 and '407 patents, but not those of the '760 patent). Also, the Partial Covenant would not apply if Lannett were ever to make a change to its NUMBRINO product, no matter how insignificant or irrelevant the change is to anything relating in any way to Genus's patents.

Lannett therefore faces the same dilemma Apotex faced in *AstraZeneca*. If this Court were to dismiss Lannett's counterclaims, with Genus continuing to demand that Lannett pay substantial royalties for a license to its "current and future patents covering cocaine hydrochloride" (*i.e.*, its Orange Book-listed patents), and the implicit threat that comes with such demands, Lannett would be forced to choose between continuing to sell its cocaine hydrochloride products at risk of being found to have thereby infringed Genus's as yet unasserted patents, or cease selling them even though it believes it has the right to do so.

By granting a covenant so carefully crafted and restricted in order to preserve its ability to sue Lannett for infringement in numerous different circumstances on numerous different patents and patent claims, Genus has demonstrated its true intent here, and that covenant serves to highlight the reasons why Lannett needs clarity regarding its freedom to continue selling its

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changes based on new safety information); Ex. 9 (FDA Guidance Doc.).

cocaine hydrochloride products. The Court can and should adjudicate all of Lannett's counterclaims, and thereby provide clarity with respect to the parties' respective rights regarding Lannett's ongoing sales of its cocaine hydrochloride products.

B. This Court Has Jurisdiction Over Lannett's Counterclaims Directed to Genus's As Yet Unasserted Orange Book-Listed Patents

Genus next argues there is no actual controversy as to Genus's as yet unasserted Orange Book-listed patents (*i.e.*, the '843, '961, and '505 Patents) because it has never made any overt threats against Lannett with respect to those particular patents. D.I. 13 at 10-11. But Genus's argument ignores (a) that Genus has demanded that Lannett pay substantial royalties for a license to practice its "current and future patents covering cocaine hydrochloride"—*i.e.*, its Orange Book-listed patents; (b) that the three as yet unasserted Orange Book listed patents are part of the same patent family, cover the same technology, and recite many of the same claim limitations as the three patents that Genus does now assert; and (c) that by listing these patents in the Orange Book, Genus has represented to the FDA that it could reasonably assert a claim of patent infringement against any entity—such as Lannett—that makes and sells a cocaine hydrochloride solution product without a license (*see* 21 U.S.C. § 355(b)(1)).

There is thus a definite and concrete dispute between the parties as to all of Genus's Orange Book-listed patents, not just those that Genus has chosen—for now—to assert against Lannett. As the Federal Circuit held in *Revolution Eyewear*, an Article III case or controversy arises "where a party asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where the party contends that it has the right to engage in the accused activity without a license." 556 F.3d at 1297.

"Even under the now-discarded reasonable apprehension of suit test, it was well established that a sufficient controversy exist[s] for declaratory judgment jurisdiction where the

patentee had accused the declaratory judgment [claimant] of misappropriating the same technology in related litigation." *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1358 (Fed. Cir. 2013). *See also Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("Our conclusion supports what we have already established in non-ANDA cases—that related litigation involving the same technology and the same parties is relevant in determining whether a justiciable declaratory judgment controversy exists on other related patents"). "When an actual controversy exists over one patent, it can also cover patents relating to the same technology between the parties." *Nexans Inc. v. Beldan Inc.*, 966 F. Supp. 2d 396, 402 (D. Del. 2013) (upholding jurisdiction where the two patents "possess[ed] the same title, the same inventors, and substantially the same specification"); *see also DNP Int'l Co. v. Natural Alternative Int'l Inc.*, No. 11-1283-GMS, 2013 WL 12221938, at *1 n.1 (D. Del. Feb. 27, 2013). For this reason, "Courts have held that a patentee's accusing a party in litigation of infringing its patents can give rise to jurisdiction for the accused party to bring declaratory judgment claims with respect to related patents of the patentee." *Dror v. Kenu*, No. 19-cv-03043-LB, 2019 WL 5684520, at *9 (N.D. Cal. Nov. 1, 2019) (citing *Arkema* and denying motion to dismiss for lack of subject matter jurisdiction). That is particularly true where—as here—the party has refused to provide concrete assurance that it will not bring suit on the other, related patents and has also sued the defendant for alleged Lanham Act violations and alleged unfair competition on related subject matter. *DNP*, 2013 WL 12221938, at *1 n.1.

Here, all of Genus's patents relate to the same technology—*i.e.*, cocaine hydrochloride solutions used to treat patients undergoing diagnostic or surgical procedures through their nasal cavity. That indisputable fact is confirmed by the fact that Genus listed all six patents in the Orange Book for GOPRELTO, and that they are all part of the same patent family, with the same

named inventors, Title and Abstract, and substantially overlapping specifications and claims.

Thus, under the cases cited above, a case or controversy between the parties exists not only as to the three patents that Genus has already asserted against Lannett, but also as to Genus's three additional, as yet unasserted Orange Book-listed patents. Indeed, if Genus had obtained FDA approval for GOPRELTO before Lannett filed its NDA for NUMBRINO, the FDA likely would have required Lannett to seek such approval via an Abbreviated New Drug Application ("ANDA"), rather than via a 505(b)(2) NDA.[11] And if that had been the case, then under the Hatch-Waxman Act, Lannett would have had a statutory right to assert declaratory judgment claims for any Orange Book-listed patents on which Genus did not bring suit. *See* 21 U.S.C. § 355 (D)(i)(II) (in Section entitled "Civil action to obtain patent certainty").

Moreover, by not including the as yet unasserted Orange Book-listed patents in its Partial Covenant, Genus has deliberately retained the ability to sue Lannett in the future on those patents, hoping to keep them in its back pocket to use against Lannett at a time and place of its choosing. In other words, Genus wants them available for use as the next chess move in its ongoing litigation campaign against Lannett. Thus, as in *Arkema*, Genus's decision not to grant a covenant not to sue as to these three as yet unasserted Orange Book-listed patents "further suggests that there is an active and substantial controversy between the parties regarding their legal rights with respect to those patents." *Arkema*, 706 F.3d at 1358.

Genus ignores this well-established body of case law, instead relying on the District of Massachusetts' inapposite decision in *Applera Corp. v. Michigan Diagnostics, LLC*, 594 F. Supp. 2d 150 (D. Mass. 2009). *See* D.I. 13 at 10-11. There, Applera sued Michigan Diagnostics for infringement of three of its patents, and in reply, Michigan Diagnostics filed declaratory

[11] *See, e.g.*, Ex. 10 (FDA Guidance Doc.) at 5.

judgment counterclaims asserting non-infringement as to the entirety of Applera's patent portfolio, encompassing 62 additional patents. *Id.* at 154, 160. There was no indication, however, that any of the patents in the rest of Applera's portfolio bore any relation to the patents on which Applera sued or the product at issue. Thus, the facts presented in *Applera* bear no resemblance to those presented here, and nothing in *Applera* suggests that this Court lacks jurisdiction to hear Lannett's counterclaims directed to Genus's as yet unasserted patents.[12]

Genus also argues that "[t]he only particularized allegations of infringement that exist are in Genus's Complaint and Lannett has failed to allege otherwise." D.I. 13 at 11. But "a specific threat of infringement litigation by the patentee is not required to establish jurisdiction…" *ABB Inc.*, 635 F.3d at 1348. Moreover, Lannett can take no solace in the fact that Genus has not yet *overtly* threatened to sue on the unasserted Orange Book-listed patents, as Genus commenced this suit before issuing any express threat specific to any of its patents, thereby demonstrating Genus's propensity to shoot first and asks questions later. The existence of the additional, as yet unasserted Orange Book-listed patents hanging over Lannett's head as a Sword of Damocles is enough to serve Genus's strategic purposes in its multi-front litigation campaign to protect GOPRELTO from competition. The fact that Genus provided a limited covenant preserving its right to enforce those patents against Lannett, and continues to demand that Lannett pay royalties to license those patents, demonstrates that there exists an actual controversy that the Court can and should resolve.

[12] Genus's passing reference to *In re Qualcomm Litig.*, No. 17-cv-00108-GPC-MDD, 2017 WL 5985598, at *18 (S.D. Cal. Nov. 8, 2017), as rejecting an argument that Qualcomm's assertion in licensing negotiations of its entire portfolio of thousands of patents is sufficient to create declaratory judgment jurisdiction as to all such patents, is inapposite for similar reasons.

C. Lannett Has Established Subject Matter Jurisdiction for Its Declaratory Judgment Claims Relating to C-TOPICAL

Finally, Genus asserts that the Court lacks jurisdiction to adjudicate Lannett's counterclaims as to its prior C-TOPICAL product. D.I. 13 at 11-14. Genus is wrong.

Genus does not dispute, nor could it, Lannett's allegation that its accused NUMBRINO product "is made with the same components, using the same manufacturing process, and is packaged in the same containers as C-TOPICAL was." D.I. 6 (Lannett Counterclaims), ¶ 12. Moreover, the two products are administered in exactly the same way, for the same purpose, in connection with the same types of medical procedures. *See supra* at 5-6. In others words, although it is true that the labels for the two products are not identical, it is undisputed that the two products themselves are identical, and that they are used and administered in identical ways.

Accordingly, Lannett's C-TOPICAL product is just as susceptible to Genus's erroneous patent infringement claims as its NUMBRINO product is, and just as an actual controversy as to the invalidity and non-infringement of Genus's Orange Book-listed patents exists with respect to NUMBRINO, an actual controversy also exists as to C-TOPICAL. If it did not, then why did Genus choose to exclude C-TOPICAL from the Partial Covenant it gave to Lannett? The question answers itself: because Genus wants to preserve its ability to sue Lannett with respect to C-TOPICAL in the future, at a date, time and place of its choosing when it suits Genus's strategic interests. If Genus does not believe it has a patent infringement claim against Lannett with respect to C-TOPICAL, then it can give Lannett an unequivocal covenant not to sue to that effect. Otherwise, Lannett should not be forced to sit by and wait for Genus to execute the next move in its multi-front litigation campaign to prevent competition for its GOPRELTO product. The time for the parties to bring any patent claims they may have against each other relating to cocaine hydrochloride products is now.

None of the cases cited by Genus have any bearing on the circumstances here. In *Essai, Inc. v. Delta Design, Inc.*, for example, the court dismissed Essai's declaratory judgment complaint where the patentee had never identified any particular product that Essai sold as allegedly infringing any of its patents. No. 13-02356 JSW, 2013 WL 6248393, at*3 (N.D. Cal. Dec. 3, 2013). Here, by contrast, Genus has actually filed suit alleging that a product identical to C-TOPICAL, that is used and administered in the same way as C-TOPICAL, infringes at least three of its Orange Book-listed patents.

Unisense Fertilitech A/S v. Auxogyn, Inc. is inapposite for similar reasons. Unisense filed a declaratory judgment action after it had received letters from Auxogyn expressing concern that scientific publications and presentations by Unisense might induce unspecified third parties to infringe Auxogyn's patents in unspecified ways. 896 F. Supp. 2d 822, 825, 827-28 (N.D. Cal. 2012). Thus, "no specific instances of potentially infringing activity or concrete steps towards potentially infringing activity [had] been identified and no product [had] been accused of necessarily infringing on the '906 Patent." *Id.*at 830. Not surprisingly, therefore, the court found there was no "definite and concrete" controversy sufficient to sustain its jurisdiction over Unisense's claims—Auxogyn had not identified any alleged infringer or infringing product, and "[w]here no one is engaging in potentially infringing conduct, there is no support [for] declaratory judgment jurisdiction to test the validity of a patent." *Id.*

In *Perma-Liner Indus., Inc. v. LMK Enters., Inc.*, the court dismissed the plaintiff's claim for a declaration of non-infringement regarding a modified version of a product previously found to infringe, where the patentee was not aware of that product prior to the lawsuit and the plaintiff itself alleged there were "substantial difference[s]" between its original and modified products. No. 8:ll-CV-22-T-17AEP, 2011 WL 2693911, at *1, *6 (M.D. Fla. July 12, 2011). Here, Genus

is well aware of C-TOPICAL, and C-TOPICAL is identical to, and used and administered in the same way as, as the NUMBRINO product that Genus accuses of infringement.

Finally, Genus argues that even if the Court could exercise jurisdiction over Lannett's non-infringement counterclaims insofar as they relate to C-TOPICAL, it should decline to do so because "Lannett is not currently selling C-Topical and cannot sell it in the future." D.I. 13 at 13-14. However, the fact that Lannett is no longer selling C-TOPICAL does not eliminate the live dispute between the parties, as the six year statute of limitations for patent infringement claims (*see* 35 U.S.C. § 286) allows Genus to sue Lannett for alleged infringement based on its past sales of C-TOPICAL. Moreover, C-TOPICAL is key prior art to Genus's patent, and thus will be before the Court and the jury in any event.

Genus cites *Benson v. Amguard Ins. Co.* as an instance of this Court exercising its discretion to decline jurisdiction because adjudicating past conduct would "serve no useful purpose." No. 16-196-LPS, 2017 WL 2672078, at *3 (D. Del. June 21, 2017). The facts in that case, however, bear no resemblance to those presented here. In *Benson*, an injured worker who had filed for and received workers compensation benefits nevertheless sought a declaration that the defendant insurance company's handling of his claim evinced a "profound indifference" to his contractual rights and general well-being. *Id.* at*1. Neither *Benson*, nor any other case Genus cites, suggests that a court should decline to adjudicate a disputed issue as to whether a past product infringes a plaintiff's patents, when the plaintiff itself is asking the court to adjudicate whether another product, that is identical to and used in the same way as the previously-sold product, infringes those same patents. To the contrary, principles of judicial economy dictate that in such circumstances, court should decide those issues in a single action.

III. CONCLUSION

For the foregoing reasons, the Court should deny Genus's Motion to Dismiss.

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Respectfully submitted,

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